

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2142856	(X3) Date Survey Completed 01/18/2024
Name of Provider or Supplier Blue Sky Fertility	Street Address, City, State 14253 Metcalf Ave, Overland Park, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, manufacturer's instructions, laboratory procedure, and technical supervisor (TS) interview, the laboratory failed to obtain and/or document QC results that met the laboratory's and manufacturer's criteria for acceptability before reporting patient test results for semen analysis. Findings: 1. Review of "Daily Quality Control Log" entries for the year 2023 revealed under: Stain Change: a.. No documentation of acceptable stain quality was provided in this section. b.. No documentation of acceptable stain quality was provided at the time of survey for the year 2023. 2. Review of the SCOPESCREEN QC-Beads instructions revealed the following expected values using the Micro-Cell counting chamber: a. Hi QC-Beads 30-40 million beads/ml. b. Lo QC-Beads 15-21 million beads/ml. 3. Review of "Daily Quality Control Log" entries for the year 2023 revealed under: Accubead Check: a. All entries were "yes." b. No documentation of obtained QC values was provided at the time of survey. c. No documentation of repeat testing, corrective action for unacceptable results, or acceptability was provided at the time of survey. d. The TS stated that it is common to have to perform the QC numerous times before an acceptable count is attained so the testing personnel (TP) only document when the QC values are acceptable and not the actual values. 3. Review of the "Quality Control in the Laboratory" procedure revealed under Procedure: B): "Accubeads will be counted each day that andrology testing is performed. Two counts will be performed on the Standard Count Microcell chamber as a patient sample is counted, and if within acceptable range, will be checked "ok" upon the QC checklist. If the sample is out of range, it will be remixed, and recounted. If the sample</p>

continues to fall outside of the acceptable range, it may be necessary to replace the Standard Count Microcell chamber, and patient testing should be discontinued utilizing that counting chamber." 4. Records of QC result failures were needed to address test supply issues, need for additional training of testing personnel and corrective actions. 5. Records of stain quality acceptability were needed to address problems with the staining solution which could impact patient results. 6. There were 500 semen analysis patient results reported in the year 2023. 7. Interview with the TS on 1/18/24 at 11:20 a.m. confirmed the laboratory failed to obtain and/or document QC results that met the laboratory's and manufacturer's criteria for acceptability before reporting patient test results for semen analysis.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of QC procedure, QC records for lutenizing hormone (LH) performed on the TOSOH analyzer from 6/1/23 to 6/30/23, lack of acceptable QC values, lack of corrective action documentation, lack of patient remediation documentation for LH patient results and interview with TS, the laboratory failed to evaluate LH patient test results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action.
Findings: Review of "Quality Control in the Laboratory" procedure revealed under Procedure D) "At least 2 levels of quality control will be processed for each endocrinology test performed in each 24 hour period. Each level should fall within 3 SD of the established range. If the level(s) does not fall within the established range, it should be repeated. If still falls outside of the indicated range, all patient results should be held until corrective action can be performed. All corrective action should be documented." 1. Review of LH QC records from the TOSOH analyzer revealed: a. Unacceptable QC values for level 2 on 6/14/23 and 6/15/23. b. Under comments for 6/14/23 was "ctrl 2 reran." No comments were present for QC values on 6/15/23. c. No documentation of acceptable QC level 2 for 6/14/23 and 6/15/23 was provided at the time of survey. d. No documentation to demonstrate LH patient testing was not performed or results were evaluated for possible corrective action was provided at the time of survey. e. No corrective action documentation was present including notification to the provider and patients of results, and orientation/training for the performing TP was provided at the time of survey. 2. Review of patient test results revealed eight LH patient results were reported without evaluation for the unacceptable QC. 3. Interview with TS on 1/18/24 at 1:30 p.m. confirmed, the laboratory failed to evaluate LH patient test results since the last acceptable QC test run to determine if patient results had been adversely affected and may require corrective action.